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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/773,815 | 02/06/2004 | Lukas Eisermann | 31132.40 | 8264 |

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| EXAMINER |
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PELLEGRINO, BRIAN E

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| ART UNIT | PAPER NUMBER |
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3738

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/17/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/773,815

Applicant(s)

EISERMANN ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/10/04, 8/20/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group II (method of implanting a spinal device) in the reply filed on 10/27/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12,13,20,22,24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochshuler et al. (6045579). Fig. 5 shows a spinal device with first and second members **12,14** and connecting members **30,32** coupled between the first and second members. Hochshuler et al. disclose that fusion devices are inserted into disc space after the intervertebral disc has been removed, col. 1, lines 23-26. Hochshuler et al. additionally discloses the device is to be used for lateral deviations, col. 4, lines 25-27, col. 8, lines 19,20. Hochshuler also discloses the connecting members are rotated to move the vertebral members and vertebrae with respect to one another, col. 3, lines

13-17, col. 9, lines 19-36. Fig. 6A shows the connecting member and the examiner is interpreting the claimed elements "rod" in this way: a rod as a straight piece or bar of material. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. Thus the connecting member can be a "rod".

Claims 22,24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kambin (5665122). Fig. 4 shows a first member **16** engaging a first vertebra and a second member **17** engaging a second vertebra. Fig. 5 illustrates the device has a connecting member **30** that is positioned within the device and vertebrae. Kambin discloses the connecting member is then rotated to move the vertebrae relative to one another, col. 4, lines 7-9. Kambin also discloses the device can be inserted in a "substantial lateral" approach to the spine, col. 3, lines 16-20. It can be construed that the device permits some articulation as illustrated by the structure shown in Fig. 6. Regarding claim 27, after rotating the connecting member, an implant is inserted between vertebrae, (see Figs. 1-3) such that a second implant is inserted after the first is rotated.

Claims 22,23,28,30 are rejected under 35 U.S.C. 102(a) as being anticipated by Nohara et al. (EP 1222900). Nohara et al. disclose the method of correcting spondylolisthesis between vertebrae by engaging a first spinal member with a first vertebra and engaging a second spinal member with a second vertebra, Fig. 1. It can be seen that first and second screws **5** are inserted into the spinal vertebrae and that a connecting member (**1**) is coupled to the first and second spinal screws. Nohara et al.

also disclose that the connecting member can be rotated to move the vertebrae, col. 3, lines 23-29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12,13,20-22,24-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hochshuler et al. (6045579). Hochshuler et al. is explained as above. However, in the alternative Hochshuler does not explicitly disclose inserting the upper and lower vertebral members laterally into the vertebrae and that a rotatable wrench is used to rotate the connecting member. It is well known in the art that spinal devices can be inserted into the vertebrae in a lateral procedure. It would have been obvious to one of ordinary skill in the art to utilize a lateral approach to correct the lateral deviation in the method of Hochshuler et al. using the spinal device with a rotatable connecting member. With respect to claim 21, it would have been an obvious expedient to use a rotatable wrench to rotate the connecting member as such only involves routine skill in the art.

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (2004/0138749) in view of Marnay (5314477). Fig. 1A shows a spinal device with first and second members having offset laterally-extending keels.

Zucherman et al. disclose a method of insertion where the intervertebral disc has been removed, paragraphs 54,55. Fig. 1B illustrates a rotatable member 134 of which the Examiner is considering to be the connecting member since it engages the first member and is part of the second member. Please note claims are given their broadest reasonable interpretation. Zucherman also discloses a tool is used to rotate the implant members, paragraph 51. However, Zucherman et al. do not explicitly disclose that the procedure or insertion of the spinal device is done laterally or forming slots in the vertebrae. Marnay teaches to form lateral slots in the vertebrae and thus the implant is then inserted laterally, col. 3, lines 7-13,17,18,48-50, col. 7, lines 37,52,53. It would have been obvious to one of ordinary skill in the art to use the method of forming slots for the keels laterally as taught by Marnay in the method of inserting the spinal implant of Zucherman et al. such that it does not cause any problems of placement of the implant and is easily inserted since the site is prepared.

Claims 12,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nohara et al. (EP 1222900) in view of Howland (5545164). Nohara et al. is explained supra. However, Nohara et al. fail to disclose that the spinal disc is removed. Howland shows (Fig. 7) a spinal system including bone screws and a connecting member. Howland also teaches that the intervertebral disc can be removed when using this type of spinal repair system, col. 4, lines 20-24. It would have been obvious to one of ordinary skill in the art to remove disc material if necessary as taught by Howland when performing the procedure of Nohara et al. and inserting bone screws and a connecting member such that no further damage is done and the diseased tissue does not spread.

Claims 18,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nohara et al. (EP 1222900) in view of Howland '164 as applied to claim 17 above, and further in view of Wagner et al. (6030389). Nohara et al. as modified by Howland is explained supra. However, Nohara in view of Howland fail to disclose the type of screws used in the surgical procedures. Wagner et al. teach that there are two types of screws used in spinal stabilization procedures, bi-cortical and uni-cortical and enable the surgeon to decide which to use based on the type of device the screws are used with, col. 1, lines 31-44. It would have been obvious to one of ordinary skill in the art to utilize either bi-cortical or uni-cortical as taught by Wagner et al. in the method of spinal repair with the device of Nohara et al. as modified by Howland such that the implantable screws and connectors remain in place and provide the proper alignment for the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (7:30am-5pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Brian E. Pellegrino", written in a cursive style.